4139. Misbranding of X-O-Kreme ointment. U. S. v. 131 Jars, etc. (F. D. C. No. 34932. Sample No. 2748–L.)

LIBEL FILED: April 6, 1953, Southern District of Florida.

ALLEGED SHIPMENT: On or about October 6, 1952, by the Wright Pharmacal Co., from Birmingham, Ala.

PRODUCT: 131 1-ounce jars of *X-O-Kreme ointment* at Miami, Fla., together with a number of circulars entitled "New Wonder Drug Discovered."

LABEL, IN PART: (Jar) "X-O Kreme Ointment Contains: 1% Hexachlorophene, 1% Dichlorophene, Zinc Oxide and Lanolin in White Petroleum base."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned circular were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for resistant skin infections, sores, facial blemishes, and burns, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: May 4, 1953. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE*

4140. Misbranding of liniment. U. S. v. 2 Dozen Bottles, etc. (F. D. C. No. 33585. Sample No 36208–L.)

LIBEL FILED: September 10, 1952, Eastern District of Kentucky.

ALLEGED SHIPMENT: On or about June 30, 1952, by the Dr. Reed Liniment Co., from Portland, Ind.

PRODUCT: 2 dozen 12-ounce bottles of *liniment* at Lexington, Ky., together with a number of booklets headed "Foreword." Examination showed that the article contained 2.2 percent of bichloride of mercury instead of 0.0267 percent as represented.

LABEL, IN PART: (Bottle) "Dr. J. W. Reed's Absorbent Liniment * * * Contents Bichloride of Mercury, .0267% by weight; Turpentine; Gum Camphor; Muriatic Acid; Coloring Matter; Logwood Chips or Fl. Ext. Baptisia; Ethyl (Denatured) Alcohol, 80% by volume."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the accompanying booklets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for bone spavin, thoroughpin, capped hock, shoe boils, wind or road puffs, bunches of all kinds, lameness from any cause, weak joints, sweeny, rheumatism, fistula, poll evil, synovial bursae, big knee, sprains, grease heel, quarter crack, corns, cockle ankle, sprung knees, lump jaw, nail wounds, and open joints. The article was not an adequate and effective treatment for those conditions.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear a statement of the quantity or proportion of bichloride of mercury contained therein since the label declaration of the quantity of bichloride of mercury contained in the article was inaccurate.

DISPOSITION: October 9, 1952. Default decree of condemnation and destruction.

*See also No. 4128.

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4141–4160

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *June 17, 1954.*

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*For presence of a habit-forming narcotic without warning statement, see Nos. 4141–4144; omission of, or unsatisfactory, ingredients statements, Nos. 4141–4143, 4145, 4146; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4141–4145; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4141–4143, 4145.

300099—54——1

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4141. Misbranding of Seconal Sodium capsules, amphetamine hydrochloride tablets, dextro-amphetamine sulfate tablets, and pentobarbital sodium capsules. U. S. v. Charles J. Bridgman (Bridgman Drug), and Otto A. Greiser. Pleas of nolo contendere. Defendant Bridgman fined $900 and Defendant Greiser placed on probation for 6 months. (F. D. C. No. 33726. Sample Nos. 35050–L, 35054–L, 35414–L, 35415–L, 35422–L, 35423–L.)

INFORMATION FILED: May 4, 1953, Southern District of Iowa, against Charles J. Bridgman, trading as Bridgman Drug, Des Moines, Iowa, and against Otto A. Greiser, an employee of Mr. Bridgman.

ALLEGED VIOLATION: On or about November 19 and 26 and December 4 and 5, 1951, while a number of *Seconal Sodium capsules, amphetamine hydrochloride tablets, dextro-amphetamine sulfate tablets,* and *pentobarbital sodium capsules* were being held for sale at Bridgman Drug, after shipment in interstate commerce, the defendants caused various quantities of such drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* and *pentobarbital sodium capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and such repackaged drugs failed to bear labels containing the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the labels of the repackaged *amphetamine hydrochloride tablets* and *dextro-amphetamine sulfate tablets* failed to bear the common or usual name of each active ingredient of such drugs; and, Section 502 (f) (2), the labeling of the repackaged *amphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 4, 1953. The defendants having entered pleas of nolo contendere, the court fined Defendant Bridgman $900 and placed Defendant Greiser on probation for 6 months.

4142. Misbranding of methyltestosterone tablets, phenobarbital tablets, and amphetamine sulfate tablets. U. S. v. Goldberg Drug Store, Edward J. Rubas, and John Tarczewski. Pleas of guilty. Fine of $500 against store and fine of $250 against each individual, plus costs. (F. D. C. No. 33843. Sample Nos. 9448–L, 33531–L, 33537–L to 33539–L, incl., 33543–L to 33545–L, incl.)

*See also No. 4157 (veterinary preparation).